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MAR 1 2013

510(k) Summary

Submitter's Name and Address:	Scion Medical Technologies, LLC 90 Oak Street Newton, MA 02464 U.S.A.
Contact Name and Information:	Joseph Ostendorf Regulatory Affairs Consultant Scion Medical Technologies Address: 23879 Blue Spruce Road Sauk Centre, MN 56378 U.S.A. Telephone: (503) 784-6756 Fax: (888) 582 – 6211 E-mail: jeostendorf@gmail.com
Date Prepared:	**20 November 2012**
Proprietary Name(s):	**CASSI™ II Rotational Core Biopsy System**, with the **CASSI QuadPoint™ Disposable**
Common Name:	**Biopsy instruments and accessories**
Product Code:	**KNW**
Classification of Device:	**Class II, 21 CFR 876.1075**
Predicate Device:	Sanarus CASSI™ II Rotational Core Biopsy System — K051581 — July 27, 2005
Device Description:	The proposed CASSI II Rotational Core Biopsy System consists of the following primary components: a fully integrated control unit handle (the CASSI II handle), a valve block, battery, cryogen, a biopsy needle (CASSI QuadPoint comprised of a sticking needle and cutting cannula/piston assembly), and a sample collection tray. The sticking needle is operated by the control unit and uses cold temperatures at its tip to engage the tissue to be sampled. The cutting cannula is coaxially mounted around the sticking needle and is used to core the tissue specimen. The cutting cannula is available in two sizes (10 and 12 gauge).

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Indications for Use:	The device is indicated for use in obtaining biopsies from soft tissues such as liver, kidney, prostate, spleen, lymph nodes and various soft tissue tumors. It is not intended for use in bone. The device is also indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities. It is designed to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality. The extent of histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality (e.g., malignancy). When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.
Technological Characteristics:	The purpose of this premarket notification is to seek clearance for an updated branding and packaging configuration to the Sanarus CASSI II Rotational Core Biopsy System (K051581) and to summarize minor modifications made to the device since the last submission. The modified device will be marketed under the trade names CASSI II Rotational Core Biopsy System and the CASSI QuadPoint disposables.
Conclusion:	In summary, Scion Medical Technologies, LLC believes that the proposed CASSI II Rotational Core Biopsy System and the CASSI QuadPoint disposables, as described in this submission, do not raise any new or significant questions of safety and efficacy and are substantially equivalent to the predicate Sanarus CASSI II Rotational Core Biopsy System, which was determined to be substantially equivalent and cleared on July 27, 2005 (K051581).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 1, 2013

Scion Medical Technologies, LLC
% Mr. Joseph Ostendorf
Regulatory Affairs Consultant
Ostendorf Consulting
23879 Blue Spruce Road
SAUK CENTRE MN 56378

Re: K123606
Trade/Device Name: CASSI™ II Rotational Core Biopsy System with the CASSI QuadPoint™ Disposable
Regulation Number: 21 CFR§ 876.1075
Regulation Name: Gastroenterology-urology biopsy instrument
Regulatory Class: II
Product Code: KNW
Dated: January 25, 2013
Received: January 31, 2013

Dear Mr. Ostendorf:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies.
You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to
http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address
http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Herbert P. Lerner -S

for

Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known):

Device Name:

CASSI™ II Rotational Core Biopsy System with the CASSI QuadPoint™ Disposable

Indications For Use:

The device is indicated for use in obtaining biopsies from soft tissues such as liver, kidney, prostate, spleen, lymph nodes and various soft tissue tumors. It is not intended for use in bone.

The device is also indicated to provide breast tissue samples for diagnostic sampling of breast abnormalities. It is designed to provide breast tissue for histologic examination with partial or complete removal of the imaged abnormality. The extent of histologic abnormality cannot be reliably determined from its mammographic appearance. Therefore, the extent of removal of the imaged evidence of an abnormality does not predict the extent of removal of a histologic abnormality (e.g., malignancy). When the sampled abnormality is not histologically benign, it is essential that the tissue margins be examined for completeness of removal using standard surgical procedures.

Prescription Use ___X___ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Herbert P. Lerner -S

(Division Sign-Off)
Division of Reproductive, Gastro-Renal, and Urological Devices
510(k) Number K123606